Description of the device

I. Product Name: *Instant-View™* Fecal Occult Blood Rapid Test

II. Manufacturer:

Alfa Scientific Designs, Inc.
12330 Stowe Drive
Poway, CA 92064
Telephone: (858) 513-3888
Fax: (858) 513-8388
Email: info@alfascientific.com

III. Common Name of the Device: Fecal Occult Blood (FOB) Test

IV. Trade Name of the Device: Instant-View™ Fecal Occult Blood Rapid Test

V. Establishment Registration Number: 2060833.

VI. Classification of the Device:

The Test Device is classified as Class II (21 CFR 864.6550).

VII. Intended Use:

This Fecal Occult Blood (FOB) Rapid Test is an immunochemical device intended for the qualitative detection of Fecal Occult Blood by laboratories or physicians offices. It is useful to determining gastrointestinal (GI) bleeding found in a number of gastrointestinal (GI) disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.
This test is recommended for use in 1) routine physical examinations, when hospital patients are first admitted, 2) hospital monitoring for bleeding in patients, 3) screening for colorectal cancer or gastrointestinal bleeding from any source.

VIII. Predicate Product:

Hemoccult® test by Beckman Coulter, Inc., 510K# K880499.

IX. Performance Summary:

The *Instant-View™* FOB Rapid Test is more accurate than the predicate device Hemoccult®. The performance of *Instant-View™* FOB Rapid Test was verified by sensitivity, specificity, cross reactivity, interference, reproducibility and accuracy studies. Please refer the attached "Summary".

Device specifications

I. BACKGROUND

The American Cancer Society and National Cancer Institute guidelines for early detection of colorectal cancer recommend an occult blood stool test annually every 3-5 years after age 50 years. There are three types of tests for FOB testing are commercially available: 1) Guaiac Dye; 2) Immunochemical; and 3) Hemoporphyrin. The Guaiac test is widely available, but lack of high accuracy. The Hemoporphyrin test is not affected by dietary peroxidases, but false-positive results can occur in patients with upper gastrointestinal bleeding disorders. This Immunochemical FOB test has great advantage than the Guaiac and Hemoporphyrin method. It is highly accurate, and the results are not interfered by dietary peroxidases, animal blood and ascorbic acid.

II. PERFORMANCE CHARACTERISTICS

1. Sensitivity and prozone effect study

The Instant-View™ FOB Rapid Test is able to detect the human Hemoglobin (hHb) at the level close to or higher than 50μg hHb/g feces (50ng/ml extraction buffer) and no interference from prozone effect was observed when the human hHb level reached up to 2000ng hHb/ml, which is equivalent to 2mg hHb/g feces.

A sensitivity study was conducted in-house to evaluate the minimum concentration of the human hemoglobin that has a high probability of being detected with this devise.

Forty stool extraction samples were spiked with human hemoglobin at five levels of concentrations, 0, 37.5, 50, 62.5, and 2000ng/ml, in an evenly distributed number, 8 of each level. The samples were blind labeled and tested with three lots of *Instant-View ™* Fecal Occult Blood Rapid Test. Results were compared with one lot of predicate device, the Hemoccult® Test.

Results indicated that the *Instant-View ™* Fecal Occult Blood Rapid Test has a sensitivity of 50 ng/ml, and 100% agreed with predicate device.

2. Specificity study

Cross reactivity

The Instant-View™ FOB Rapid Test was examined in vitro by adding hemoglobin (Hb) of beef, chicken, fish, horse, goat, pig, rabbit, and sheep to the human feces and applied to the test to determine the cross-reactivity of the test with the hemoglobin from other spices. The samples were added with and without diluted hHb at 50 μg hHb/g feces. Instant-View™ FOB Rapid Test gave negative test results when tested with the Hb of other spices and positive in all cases when hHb was present. Whereas the Hemoccult® test consistently gave false-positive results when tested with all hemoglobin of other spices.

- **Interference of dietary substances**

Instant-View™ FOB Rapid Test does not require the patient to follow any special dietary restrictions. Aqueous extracts of raw broccoli, cantaloupe, cauliflower, horseradish, *Parsnip,* red radish and turnip were added to the Test device to determine if vegetable extracts cross react with the test. Test device was also tested with 20 mg/ml solution of horseradish peroxidases. The extracts were added with and without diluted hHb at 50 μg hHb/g feces (50ng/ml extraction buffer). *Instant-View*™ FOB Rapid Test gave negative results when tested with all of the extracts, and positive results when hHb was present. The Hemoccult® Test, a Guaiac FOB Test, consistently gave false-positive results to all the cases with or without human Hb. A dietary iron and Vitamin C supplement were added with and without diluted human Hb at 50 μg hHb/g feces (50ng/ml extraction buffer) to the test device. No interference was observed with the performance of the Instant-View™ FOB Rapist test.

- **Interference by toilet water**

Additives:
No false positive test results were observed with toilet bowl deodorizers/fresheners or cleaners studied. The effects of the toilet bowl deodorizers/fresheners or cleaners on the sensitivity of the test are varying. Some decreased the sensitivity of the test by over three-fold, while others have no effect. Based on the results of these studies it is concluded that toilet bowl deodorizers/fresheners or cleaners should be removed from the toilet bowl prior to collecting samples for the proposed test.

Contaminants:
Study on the contaminated toilet bowl with residual human blood indicated that the human blood left in the toilet bowl may induce false positive results, if the concentration of human blood is equal to or higher than 50ng/ml. Therefore, instructions were given that flush the toilet before use.
The specimen is suggested to be collected from the toilet paper or caught in a clean cup to avoid contacting toilet water.

3. Reproducibility and repeatability studies

One hundred (100) human hemoglobin free stool extraction specimens collected in house and divided into 5 groups in an evenly distributed number, 20 in each. The 5 groups of extraction samples were spiked with human hemoglobin for five different concentrations, respectively, 0, 37.5ng hHb/ml (25% lower than cut off), 50ng hHb/ml (cut off level), 62.5ng hHb/ml (25% higher than cut off), and 2000ng hHb/ml (equal to 2000μg hHb/g feces). Those specimens were tested with *Instant-View™* Fecal Occult Blood Test at three (3) Physician Office Laboratories (POL) and a Reference Laboratory. All specimens were blind labeled.

The results obtained from three POL sites by persons with diverse education background and work experiences agreed 97.7 % (average) with the expected results. The results obtained from the Reference laboratory agreed 99% with the expected results. Overall, the accuracy of the Instant-View™ Fecal Occult Blood Rapid Test is 98%.

4. Specimen Collection and Handling

Fresh human hemoglobin free stool extraction specimens, total 120 specimens, were collected in house and divided into 5 groups in an evenly distributed number, 72 in each group. Those 5 groups of

extraction samples were spiked with human hemoglobin for five different concentrations, respectively, 0, 37.5ng hHb/ml (25% lower than cut off), 50ng hHb/ml (cut off level), 62.5ng hHb/ml (25% higher than cut off), and 2000ng hHb/ml (equal to 2000µg hHb/g feces).

The specimens in each group were further divided into three groups, A, B, and C, 8 specimens of each concentration in each group.

Specimens of Group A were stored at temperature 95°F (35°C) and tested at 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 days post preparation. Specimens of Group B were stored at 39.2°F (4 °C) and tested at 1, 2, 3, 4, 5, 6, 7 and 8 months post preparation. Specimens of Group C were stored at –4°F (-20°C) and tested at 6, 12, 18, 20, 22, 24, 25, and 26 months post preparation. The samples were blind labeled and tested with three lots of *Instant-View ™FOB Rapid Test.* Every test result was read by two independent readers.

Results observed indicated that specimens collected may be stored up to 8 days at temperature 95°F (35°C); 6months at 39.2°F (4 °C), and at least 2 years at –4°F (-20°C).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 17 2002

Naishu Wang, M.D., Ph.D.
President
Alpha Scientific Designs, Inc.
12330 Stowe Drive
Poway, CA 92064

Re: k021423
Trade/Device Name: Instant-View™ Fecal Occult Blood Rapid Test
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult Blood Test
Regulatory Class: Class II
Product Code: KHE
Dated: April 30, 2002
Received: May 3, 2002

Dear Dr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) NUMBER (IF KNOWN): K021423

DEVICE NAME: **Instant-View™ Fecal Occult Blood Rapid Test**

INDICATIONS FOR USE:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Josephine Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021423